

We, Cantor and Nissel Ltd, Market Place, Brackley, Northamptonshire, NN13 7NN

Hereby declare under our sole responsibility that the CE marked product(s) to which this declaration relates,

Non-Sterile RGP lenses

Apex Rigid Lenses
Aqualine MF Series
Bifocal RGP Lenses
Cantor Hybrid (Formerly EyeBrid)
Cantor Hybrid Cone (Formerly EyeBrid Cone)
MetrO₂
Nissel KII Rigid
Nissel Sixteen-50
4F
Oxyflex / Percon
Toric Rigid Lenses
Custom Design – Practitioner defined parameters

Have been classified as Class IIa, according to Annex IX, rule 5,

and is in conformity with the essential requirements and provisions of the Council Directive 93/42/EEC concerning medical devices amended by Directive 2007/47/EC

and are in conformity either partly, fully with the relevant standards below:

BS EN ISO 10012:2003	BS EN ISO 10993-1:2009	BS EN ISO 11978:2014	BS EN ISO 11987:2012
ISO 13485:2003	BS EN ISO 14155:2011	BS EN ISO 14534:2015	BS EN ISO 14971:2012
BS EN ISO 15223-1:2012	BS EN ISO 19011:2011	BS EN ISO 11737-1:2006	BS EN ISO 14644-1:1999
BS EN ISO 14644-2:2000	ISO 18369-1:2009	BS EN ISO 18369-2:2012	BS EN ISO 18369-3:2006

and are subject to the procedure set out in Annex V of the Council Directive 93/42/EEC amended by Directive 2007/47/EC

Sterile Soft Lenses

Bandage Lenses	Nissel Custom Hand Painted Lenses
Cantor Cosmetics	Nissel KII Soft
Cantor Prosthetics	Nissel Naturals
ChromaGen TM	Pastel Tints
Hydrocyl Soft Toric	PV Series Multifocal Soft Lenses
Hydrofit	Thames Design
Hydrolens	X-Chrom
Meridian Toric	

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EC DECLARATION OF CONFORMITY



and are in conformity either partly, fully with the relevant standards below:

BS EN 556-1:2001	BS EN ISO 10012:2003	BS EN ISO 10993-1:2009	BS EN ISO 11978:2014
BS EN ISO 11987:2012	ISO 13485:2003	BS EN ISO 14155:2011	BS EN ISO 14534:2015
BS EN ISO 14971:2012	BS EN ISO 15223-1:2012	BS EN ISO 19011:2011	BS EN ISO 11737-1:2006
ISO 11737-2:2009	BS EN ISO 14644-1:1999	BS EN ISO 14644-2:2000	BS EN ISO 14644-4:2001
BS EN ISO 14644-5:2004	BS EN ISO 14644-6:2007	BS EN ISO 17655-1:2006	ISO 18369-1:2009
BS EN ISO 18369-2:2012	BS EN ISO 18369-3:2006		

and are subject to the procedure set out in Annex V of the Council Directive 93/42/EEC amended by Directive 2007/47/EC

This declaration is made on base of the quality assurance certificate N°. GB96/7963 delivered by Notified Body n° 0120

SGS United Kingdom Ltd,
Unit 202B
Worle Parkway
Weston Super Mare
BS22 6WA
United Kingdom

This certificate is valid only for devices released from the following site:

Cantor and Nissel Ltd
Market Place
Brackley
Northamptonshire
NN13 7NN
United Kingdom

Signature:

A handwritten signature in blue ink, appearing to be 'DC' followed by a stylized flourish.

Name: David Cantor

Date: 15th September 2015

Position: Managing Director